

Message

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Subject: Tebuconazole Meeting DFR/TTR Clarification
Attachments: Tebuconazole DCI 9.13.17.pdf; Tebuconazole Scooping Document.pdf

Good morning all,

Some of you have asked for more information about what Janelle Kay (the representative for a cost-sharing consortium for tebuconazole data development) would like to know about the DFR/TTR studies during our meeting tomorrow (see the agenda in the meeting invite). I asked her to clarify and she wrote:

"I was hoping to have a response from the contractors before I respond, but I haven't heard back yet. The TF was currently thinking of running the DFR studies on wheat and peanuts using 3.6F based on the use of tebuconazole. Since peanuts have a limited geographic use area, there was a thought we could run 2, instead of the typical 3. However, we also weren't sure if EPA considered wheat/peanuts significantly different enough. Also, the TF may have access to a grape study conducted in the EU, but with a formulation not registered in the US (and the study wasn't conducted in the US). We wanted input if EPA would even consider this study in lieu of a new study. Again, the above is preliminary, so it may change in the next day or two and I'll update you accordingly."

I also did a little digging into our rationale for asking for these studies in the GDCI (attached). According to the Scooping Document for tebuconazole (attached):

1. We don't have TTR or DFR data and estimated exposure is not minimal compared to the LOC (pg 3);

2. The LOC for tebuconazole for turf exposure is 300 and so an MOE of >3,000 is needed to negate the need for a new TTR study; our estimates show and LOC of <3,000 and so a new study is needed (pg 9);
3. While aggregate exposure is not of concern, the short-term aggregate risks need to be evaluated, because of concerns about exposure from golf course turf (pg 11);
4. Because there was an application rate error made in past FAR analysis and this effects some of the results and because of a lack of DFR data, we had to go on defaults for our modeling, and so we would like to see actual DFR data (pg 12);
5. Also, the post-application exposure LOC is 300, with an MOE of 600 for some crops, and so refinement to these numbers may be needed (pg 13).

NB: These points were drawn from a quick reading of the document and I encourage anyone with more questions to look further into the Scooping Document.

Finally, I reviewed a sampling of the REI for a few of the registrations of tebuconazole. There are over 500 registrations of tebuconazole with multiple use sites, and so this is a very brief sampling (I picked a few labels at random and scanned them for an REI):

Product	Site	REI
Nufarm Tebuconazole 3.6 F Fungicide	Peanuts and grasses for seed	12 hrs
Elite® 45 DF Foliar Fungicide	Grapes, bananas, plantains, various nuts	12 hrs
	Appels, pears, loquat, mayhaw, quince	5 days
RAXIL® 2.6 F Seed Treatment Fungicide	BARLEY, CORN, OATS, TRITICALE, WHEAT	None
PROCEED™ CONCENTRATE	Barley, Triticale and Wheat	12 hr
Tebuconazole 4.35 SE Concentrate	roses, flowers, trees	None

Thank you,
Jon

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